UTILITY PATENT APPLICATION TRANSMITTAL (Small Entity)

AUGA01000014

Docket No.

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Total Pages in this Submission

TO THE ASSISTANT COMMISSIONER FOR PATENTS

Box Patent Application Washington, D.C. 20231

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UTILITY PATENT APPLICATION TRANSMITTAL (Small Entity)

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Docket No. AUGA01000014

Total Pages in this Submission

Application Elements (Continued)

3.	\boxtimes	Drawing(s) (when necessary as prescribed by 35 USC 113)							
	a.	☐ Formal b. ☐ Informal Number of Sheets5							
4.	×	Oath or Declaration							
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	b.	Copy from a prior application (37 CFR 1.63(d)) (for continuation/divisional application only)							
	C.								
	d.	DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. 1.63(d)(2) and 1.33(b).							
5.		ncorporation By Reference (usable if Box 4b is checked) The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.							
6 .		Computer Program in Microfiche							
2 7.		Genetic Sequence Submission (if applicable, all must be included)							
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		Accompanying Application Parts							
8.		Assignment Papers (cover sheet & documents)							
9.		37 CFR 3.73(b) Statement (when there is an assignee)							
10.		English Translation Document (if applicable)							
11.		Information Disclosure Statement/PTO-1449 Copies of IDS Citations							
12.	\boxtimes	Preliminary Amendment							
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UTILITY PATENT APPLICATION TRANSMITTAL (Small Entity)

(Only for new nonprovisional applications under 37 CFR 1.53(b))

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Accompanying Application Parts (Continued)

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Serial No.	: Unknown) Examiner: Unknown	
(Con./Div. of	08/859,891, filed: 05/21/97))	
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Title: SYSTEM AND METHOD FOR TREATMENT OF HYPOTHERMIA (As Amended)

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

PRELIMINARY AMENDMENT

In advance of the first examination in this case, Applicants request amendment of the subject application, as follows:

IN THE TITLE

Please change the title to --SYSTEM AND METHOD FOR TREATMENT OF HYPOTHERMIA--.

IN THE SPECIFICATION

Page 1, line 3, after "This", please insert --is a divisional of application serial no. 08/859,891, filed May 21, 1997, which is a continuation of application serial no. 08/419,719, which--;

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Page 1, line 4, please insert --abandoned,-- following "1990,";
Page 1, line 5, please insert --abandoned,-- following "1988," and
Page 1, line 7, please insert --abandoned,-- following "1987".
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IN THE CLAIMS

Please cancel Claims 1-25.

Please add the following claims:

- 1 26. (Added) A system for treating hypothermia, comprising:
- 2 an inflatable cover;
- an undersurface in the inflatable cover for expelling warmed air from the inflatable cover;
- 4 and
- a heater/blower assembly for inflating the inflatable cover and for maintaining the temperature of the warmed air expelled through the undersurface in the range of about 85°F to about 117°F.
 - 27. (Added) The system of claim 26, further including a drape means formed near a periphery of the inflatable cover for trapping warmed air under the inflatable cover.
 - 28. (Added) The system of claim 27, the inflatable cover having a base sheet, the undersurface being a surface of the base sheet, the drape means being an uninflatable extension of the base sheet.
 - 29. (Added) The system of claim 27, the inflatable cover having an overlaying material sheet, the drape means being an uninflatable extension of the overlaying material sheet.
 - 30. (Added) The system of claim 29, the inflatable cover having a base sheet attached to the overlaying material sheet, the undersurface being a surface of the base sheet, the drape means being an uninflatable extension of the overlaying material sheet and the base sheet.
- 1 31. (Added) The system of claim 26, wherein the undersurface includes an array of apertures for expelling the warmed air.

- 1 32. (Added) A system for treating hypothermia, comprising:
 2 an inflatable cover;
 3 an undersurface in the inflatable cover for expelling air from the inflatable cover; and,
 4 a heater/blower assembly for providing warmed air to inflate the inflatable cover and for
 5 maintaining the temperature of the warmed air in the range of about 113°F to about 121°F.
- 1 33. (Added) The system of claim 32, further including a drape means formed near 2 a periphery of the inflatable cover for trapping warmed air under the inflatable cover.
 - 34. (Added) The system of claim 33, the inflatable cover having a base sheet, the undersurface being a surface of the base sheet, the drape means being an uninflatable extension of the base sheet.
 - 35. (Added) The system of claim 33, the inflatable cover having an overlaying material sheet, the drape means being an uninflatable extension of the overlaying material sheet.
 - 36. (Added) The system of claim 35, the inflatable cover having a base sheet attached to the overlaying material sheet, the under surface being a surface of the base sheet, the drape means being an uninflatable extension of the overlaying material sheet and the base sheet.
 - 37. (Added) The system of claim 32, wherein the undersurface includes an array of apertures for expelling the air.

l	38.	(Added)	A method for treating hypothermia in a patient, using an inflatable					
2	device, comprising:							
3	deploy	deploying the inflatable device on a patient;						
1	inflati	ng the inflatabl	e device with air warmed to a temperature in the range of about 113°F					
5	to about 121°	to about 121°F; and,						
5	expell	ling warmed ai	r through a surface of the inflatable device which faces the patient.					
l	39.	(Added)	The method of claim 38, further comprising maintaining the					
2	temperature o	of the warmed a	ir expelled through the surface in a range of about 85°F to about 117°F.					
1	40.	(Added)	The method of claim 38, further comprising maintaining an average					
2	temperature o	of air under the	surface in a range of about 103°F to about 112°F.					
1	41.	(Added)	The method of claim 38, further comprising exhausting warmed air					
1	out of at least	t one side of th	e inflatable device.					
1 2	42.	(Added)	A method for treating hypothermia in a patient, using an inflatable					
	device, comp	orising:						
3	deplo	ying the inflata	able device on the patient;					
3 4		C	le device with warmed air; and					
5	expelling warmed air in the range of about 85°F to about 117°F through a surface of the							
6	inflatable de	vice which face	es the patient.					
7								
1	43.	(Added)	The method of claim 42, further comprising maintaining the average					
2	temperature	of the warmed	air expelled through the surface in a range of about 103°F to abou					
3	112°F.							

- 1 44. (Added) The method of claim 42, further comprising exhausting warmed air 2 out of at least one side of the inflatable device.
- 1 45. (Added) The method of claim 38 or claim 42, further comprising deploying a 2 drape formed at the periphery of the inflatable device to trap warmed air under the surface.

REMARKS

Claims 1-25 have been cancelled. New Claims 26-45 have been added.

This Preliminary Amendment is submitted in advance of the first examination of the subject application in order to set forth novel and unobvious subject matter that was included in the originally filed application. No new matter has been entered.

Respectfully submitted,

Reg. No. 30,298

TERRANCE A. MEADOR

word Med

Date: 16 Fare 1999

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THERMAL BLANKET

RELATED APPLICATIONS

This is a continuation-in-part of application serial no. 07,550,757, filed July 10, 1990, which is a continuation-in-part of application serial no. 07,227,189, filed August 2, 1988, which is a continuation-in-part of application serial no. 07,104,682, filed October 5, 1987.

BACKGROUND OF THE INVENTION

This invention relates to thermal blankets used in a medical setting to deliver a bath of a thermally-controlled medium to a patient.

The thermal blanket prior art is best expressed in our prior U.S. Patent No. 4,572,188 entitled "AIRFLOW COVER FOR CONTROLLING BODY TEMPERATURE." In our prior patent, a self-erecting, inflatable airflow cover is inflated by the introduction into the cover of a thermally-controlled inflating medium, such as warmed air. When inflated, the cover self-erects about a patient, thereby creating an thermal the patient, the ambient environment about characteristics of which are determined by the temperature of the inflating medium. Holes on the underside of our prior art airflow cover exhaust the thermally-controlled, inflating medium from inside the cover to the interior of Our airflow cover is intended for the erected structure. hypothermia, might as treatment of the postoperatively.

Evaluation of our airflow cover bv skilled practitioners has resulted in general approbation: the the airflow cover efficiently that and accomplishes purpose of effectively its giving We have realized, thermally-controlled bath. while our prior art airflow cover achieves objective, certain improvements to it are necessary order to realize additional clinical objectives and to enjoy further advantages in its use.

SUMMARY OF THE INVENTION

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improved the clinical usefulness of have self-erecting airflow cover by observing that controlling the contour of its inflatable portion at its head end to define a generally concave non-inflatable portion will permit a care giver to more easily observe a patent's head, face, neck and chest. Further, we have observed that Imited venting of the thermally controlled inflating medium from the edges of the cover results in more efficient, more uniform heating within the cover. also observed that it is good clinical practice to keep the area of the care site in the vicinity of the patient's head Still further, we have and face as clean as possible. observed that modification of the foot end of the selferecting airflow cover to define a non-inflatable but erectable drape section retains heat from the inflating medium to warm the patient's feet and insulate the bare skin of the feet from excessive heat from the inlet hose. Finally, we have observed that our self-erecting airflow cover may be advantageously adapted to thermally control

specific partial portions of the patient such as the legs and lower body or the arms and upper body, leaving other areas of the patient available for care and treatment. Moreover, an end portion of the cover may be adhesively attached to the patient to prevent the migration of air toward a care area. Finally, a protective sleeve may be slideably mounted on a connected heater tube adjacent the patient to prevent the heater tube from contacting the patient.

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resulted in an improved have observations These therefor in which method and blanket thermal self-erecting inflatable covering has a head end, a foot end, two edges, and an undersurface. An inflating inlet adjacent the foot (or head) end admits a thermallycontrolled inflating medium into the covering. An aperture array on the undersurface of the covering exhausts the thermally controlled inflating medium from the covering into the structure created when the covering self-erects The improvements to this basic structural upon inflation. complement include an uninflatable section at the head (or foot) end of the covering, exhaust port openings at the edges of the covering, an absorbent bib or adhesive strip attached to the covering at the head (or foot) end adjacent the uninflatable section, an uninflatable erectable drape section at the foot end of the covering, a heater tube protective cover and structural features that make the covering simple and economical to produce. In the case of an upper body covering, the positions of the inflating inlet and the uninflatable section are reversed from that of other coverings. In the case of an upper body covering, the inflating inlet is positioned at the head end of the

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covering while the uninflatable section is arranged at the foot end of the covering.

With these improvements, the thermal blanket, when delivers erected over a patient, and thermally-controlled inflating medium into the interior of structure covering the patient, thereby thermally The first improvement permits full bathing the patient. viewing of the head and face of the patient from almost any aspect around the thermal blanket. The exhaust port openings increase the rate of circulation of the inflating blanket, thereby increasing within the temperature within the structure and making the temperature distribution more uniform. The absorbent bib soaks up and retains liquids which might otherwise spread over the care site in the area of a patient's head or other body area. Such liquids can include the patient's own perspiration, blood, vomit, saliva, or liquids which are administered to the patient. The adhesive strip acts to seal the head (or foot) end of the inflated structure. The non-inflatable erectable drape section at the foot end of a covering encompassing the lower extremities retains heat around the patient's feet and insulates the bare skin of the legs The protective cover for the heater tube and/or feet. an attached heater tube from contacting the prevents patient.

From another aspect, the invention is a thermal blanket for covering and bathing a person in a thermally-controlled medium. The thermal blanket includes a flexible base sheet having a head end, a foot end, two edges, and a plurality of apertures opening between the first and second surface of the base sheet. An overlying material sheet is

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attached to the first surface of the base sheet by a plurality of discontinuous seams which form the material substantially -parallel, plurality of into a sheet inflatable chambers. A continuous seam is provided between the material sheet and the base sheet at the head (or foot) end to form a non-inflatable viewing recess at the head (or Exhaust port openings are provided through the foot) end. material sheet to vent the medium from the chambers away from the base sheet. An absorbent bib is attached to the head (or foot) end in the vicinity of the viewing recess. encompassing the lower extremities, coverings continuous seam is provided between the material sheet and the base sheet at the foot end to form a non-inflatable, erectable drape section to cover the patient's legs and/or feet.

Therefore the invention accomplishes the important objective of providing a self-erecting, inflatable thermal blanket that permits a relatively unobstructed view of a care site when in use.

Another objective is the efficient and uniform heating of the interior of the structure created when the blanket is inflated with a heat inflating medium.

A further objective is providing a covering for a patient's legs and/or feet that helps retain the heat inflating medium around the patient.

A still further objective is the provision of such a blanket with a means for maintaining the cleanliness of the care site.

A still further objective is to provide the ability to select coverings adapted for specific partial areas of the patient leaving other areas exposed for care and treatment. The advantageous simplified structure of the thermal blanket make its production straight forward and economical.

These and other important objectives and advantages will become evident when the detailed description of the invention is read with reference to the below-summarized drawings, in which:

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Figure 1 is a side elevation view of a thermal blanket constructed in accordance with a first aspect of the invention, with the blanket in use, with associated thermal apparatus indicated schematically;

Figure 2 is an enlarged top plan view of the thermal blanket opened flat;

Figure 3 is an enlarged sectional view taken along 3-3 of Figure 2;

Figure 4 is a further enlarged sectional view taken along line 4-4 of Figure 3;

Figure 5 is a partial underside view of the thermal blanket;

Figure 6 is a partial diagrammatic top plan view of a thermal blanket constructed in accordance with a second aspect of the invention, with a partially constructed foot drape;

Figure 7 is a partial projected view of a fully constructed thermal blanket of Figure 6 in use, with the patient's feet illustrated by hidden lines underlying the foot drape;

Figure 8 is a top plan view of a partially constructed thermal blanket in accordance with a third aspect of the invention, for thermally covering the pelvic area and lower extremities of a patient;

Figure 9 is a partial projected view of a fully constructed thermal blanket of Figure 8 in use;

Figure 10 is a top plan view of a thermal blanket constructed in accordance with a fourth aspect of the present invention, for thermally covering the chest and upper extremities of a patient; and

Figure 11 is a partial projected view of a fully constructed thermal blanket of Figure 10 in use.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

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When used herein, the term "thermal blanket" is intended to be interchangeable with, but not necessarily limited by, the term "airflow cover" used in our U.S. Patent No. 4,572,188, which is incorporated herein in its entirety by reference. In this description, the term "thermal blanket" is meant to invoke a self-erecting, inflatable structure for delivering a thermally-controlled inflating medium to the interior of the structure created when the thermal blanket is inflated. The purpose of the thermal blanket is to efficiently administer a uniformly thermally-controlled bath of the inflating medium to a patient within the erected structure.

Our invention is illustrated as we intend for it to be used in a first aspect without a foot drape in Figure 1. In Figure 1, a self-erecting, inflatable thermal blanket 10 has a head end 12, a foot end 14 and two lateral edges, one indicated by 15. An inflation inlet cuff 16 is connected Tto a heater/blower assembly 18 which provides a stream of heated air through a connecting hose 20. When heater/blower 18 is operated, the stream of heated air flows through the inflating hose 20 into the thermal blanket 10 through the inflation cuff 16. When the blanket is inflated, it erects itself into a Quonset hut-like structure with a quilted upper surface 21. As described below, a pattern of apertures on the undersurface of the blanket (not shown in Figure 1) convectively delivers the inflating heated air into the interior space enclosed by the erected thermal blanket.

The contour of the inflatable portion of the thermal blanket 10 is varied at the head end 12 of the blanket to provide a non-inflated blanket recess 22 in the quilted upper surface 21, which remains smooth and flat when the blanket is inflated and erected. Circulation of heating air is accelerated through the thermal blanket by exhaust port openings in the upper surface, adjacent the lateral edges of the blanket. Two exhaust ports openings are indicated by reference numeral 23. Further, a bib 24 made of an absorbent material is attached to the head end of the thermal blanket in the vicinity of inon-inflated recess 22. In fact, as shown in Figure 1, the bib 24 includes a semi-circular tab 25 that extends into the recess 22.

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As illustrated in Figure 1, the thermal blanket of the invention is inflated, erects itself into a Estructure, and bathes a patient 26 with the thermallycontrolled air used to inflate the structure. mpatient is being thermally bathed, the uninflated recess 22 permits observation of the patient's head, face, neck, and chest from almost any location with respect to the thermal Thus, if the patient is placed on a gurney or blanket 10. a bed, the head of which is against a wall, a care giver such as a nurse, intern, resident, or doctor, can keep the patient's face under observation from the foot end 14 of the thermal blanket 20. Respiration can be detected by the rise and fall of the bib and uninflated area, which rest directly on the patient's chest. Moreover, the bib 24 will provide an absorbent sink for stray, unconfined liquids in the area of the patient's head or at the head end 12 of the thermal blanket 10.

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Figure 2 is a plan view of the thermal blanket 10 opened flat to show details of its structure. illustrates the upper surface of the thermal blanket, that is the side that is visible in Figure 1. As seen, the upper surface consists of a parallel array of elongated tubes of which 30 and 32 are the lateralmost tubes, 34 is the center tube, and the tubes 38 are arrayed between one of the lateralmost tubes and the center tube. Each tube is separated from an adjacent tube by a discontinuous seam, one of which is indicated by 40. The seam 40 separates the tube 32 and its nearest adjacent neighbor 38. The discontinuous seam 40 is interrupted by passageways 42 communicating between the tubes. An interrupted seam separates every tube from one adjacent neighboring tube. The seams permit the thermal blanket, when inflated, to assume a tubular structure on the upper surface, while the ports 42 permit full circulation of the inflating medium throughout the array of tubes. The foot-end seam 45 is continuous. The tubes are inflated through the center tube 4 34 which transitions to a port 36, through which the inflation cuff 16 is inserted. The edge seams 43 are discontinuous only at the exhaust port opening locations A seal can be made between the inflation port 36 and 23. inflation cuff 16 by any conventional means, example, an o-ring, or even tape. When the inflating medium is introduced into the center tube 34, it flows laterally from the center tube into all of the other tubes through the ports 42. Near the head end 12, a continuous seam 40 defines the forward end of all of the tubes, with the seam assuming a bell-curve shape. On the head end side of the seam 40, the thermal blanket 10 is uninflatable.

The bell-shaped seam 40 thus defines the uninflatable area 22 at the head end of the thermal blanket 10, which is essentially coplanar with, or substantially parallel to, As shown in Figure 1, by the underside of the blanket. virtue of its structural integration with the rest of the thermal blanket 10, the non-inflated recess extends over the upper chest of the patient 26 when the blanket is However, since the recess 22 is uninflated, it inflated. provides a wide-angled viewing gap in the inflated contour of the upper surface 21. The gap is filled by continuation of the underside of the blanket. It is also noted that the pattern of inflatable tubes can be replaced by other suitable patterns of communicating, inflatable chambers. The tubes are preferred since they impart strength and shape to the erected bathing structure; other inflatable structures are contemplated, however.

The absorbent bib has an indent 44 cut into its outside edge, which permits the blanket to be drawn up to the chin of a patient and which provides absorbency laterally up the neck of the patient. The absorbent bib can consist of any absorbent material such as a single- or multi-ply tissue paper which is used to make paper towels.

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Construction details of the thermal blanket 10 are illustrated in Figures 3 and 4. The thermal blanket 10 is assembled from a base sheet consisting of an underside layer 50 formed from flexible material capable of bonding to a layer 52 of heat-sealable plastic. For the layers 50 and 52, we have used a stratum of absorbent tissue paper prelaminated with a layer of heat-sealable plastic. Material of such construction is commercially available in production rolls and is used to make painters' drop

cloths. The upper side of the thermal blanket consists of a sheet of plastic bonded to the plastic layer 52 by an interruptible heat-sealing process to form the interrupted seams, one of which is indicated by 54, and the inflatable tubes, one indicated by 55. As can be seen in Figure 3, the interruption of the seam 54 forms a passageway 56 between adjacent tubes 55 and 57.

The absorbent bib and tab are shown in Figure 3 as a single material layer 60/58. Alternatively, they may be formed from separate material sheets cut to the outlines illustrated in Figure 2. The absorbent material forming the bib and tab can be bonded to the upper plastic layer by theat process or by gluing.

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The inventors also contemplate deletion of the bib and tab. In this instance, the thermal blanket would still have the viewing recess, which would be defined by the continuous seam at the head end, and which would be filled with the forward portion of the base sheet.

Circulation of heated air through the blanket Tenhanced by the exhaust port openings 23, which open through the upper plastic sheet sheet, which is heat sealed to the base of the blanket. The openings 23 vent the heated inflating air out of the outermost tubes 30 and 32, away from the underside of the blanket. Because air can circulate to, and through, the blanket edges, the inflating air in the outermost tubes is hotter than if the openings This results in hotter air being delivered were absent. through the underside apertures toward the edge of the We have measured the temperature distribution blanket. within the thermal blanket for inflating air which heated to a medium temperature range and for inflating air

which is heated to a high temperature range. The results are provided in Table I for a blanket consisting of 13 Measurements of the temperature of air exhausted through underside apertures were made on the underside of each tube on one side of the blanket. The tubes are numbered 1-6, with 1 being the tube adjacent to the center tube, and tube 6 being the outermost tube adjacent on lateral edge of the blanket. Test apertures were made in the bottom of tube 6 only for the purposes of this test. As is evident, the distribution of temperature within the Serected thermal blanket is more uniform when the exhaust port openings are provided. Further, provision of the exhaust ports also increases the average temperature within the erected structure of the blanket. Clearly, provision of exhaust port openings at the lateral edges of the blanket delivers results which one would not expect when considering the operation of our thermal blanket with no exhaust port openings.

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In our first preferred embodiment, the exhaust port Topenings are slits in the edge seams of our blanket. slits vary in length from 1-3/4 to 2 inches. Each edge seam is discontinuous approximately at each corner of the blanket so that inflating air is vented away form the underside of the erected blanket. This keeps relatively "colder" air at the blanket edges form mixing relatively "hotter" air exhausted structure through the underside apertures. The result is a "flatter" temperature profile of air within the blanket the vents, which raises the without temperature within the erected structure and makes the temperature distribution in the structure more uniform.

Resultantly, the clinical effect of the blanket is enhanced. Heating is better controlled, and more uniform, with greater comfort to the patient.

TABLE I

•	MEDIUM TI RANG	EMPERATURE SE	н	IGH TEMPERATURE RANGE
TUBE NO.	WITHOUT EXHAUST PORTS	WITH 2" EXHAUST PORTS	WITHOU' EXHAUS' PORTS	- · · ·
center (inlet) 113.3° F.	114.1° F.	121.3° F.	121.3° F.
Tube #1	109.9 ⁰	112.3°	117.3°	117.7°
Tube #2	105.30	109.8°	113.4°	115.0°
Tube #3	103.20	107.1°	111.0°	113.3°
U UTube #4	99.9 ⁰	104.3°	101.4°	108.6°
	97.2°	100.0°	95.7 ⁰	104.40
Tube #6 [(outermos	st) 85.2 ⁰	95.8 ⁰	89.6 ⁰	99.4 ⁰
Average under co	temp. ver 103.8 ⁰	106.7°	108.40	112.5°

The thermal blanket of the invention is enabled to bathe a patient in the thermally-controlled inflating medium introduced into the upper side tubes by means of a plurality of apertures 62 shown in Figures 4 and 5. The apertures extend through the underside of the blanket, which includes the layers 50 and 52. The apertures 62 are made in the footprints of the tubes of the blanket upper side according to a pattern which has been determined to deliver a very uniform thermal bath. In this regard, no apertures are provided through the underside into the lateral most tubes 30 and 32, or into the center tube 34. In addition, the apertures 62 are provided through the underside to the apertured tubes in a density which varies

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inversely with the proximity of the tube to the center tube Thus, the hole density increases from the tube 38a throughthe tube 38d. Even with the exhaust port.openings, the temperature of the inflating medium exhibits a drop from the center to the lateral most tubes. The varying density of the apertures 62 tends to reduce this gradient further by forcing hotter air to the edges of the blanket. Thus, the thermal bath delivered to the patient is of generally uniform temperature. The aperture variation also equalizes the flow of inflating medium out of the apertures. As will be evident, the inflating pressure will be greatest at the center tube 34 and will Utend to diminish toward the lateral edges of the thermal †blanket. Therefore, fewer apertures are required for the fitubes near the center tube 34 to deliver the same amount of air as the relatively greater number of apertures in the Tubes at a greater distance from the center tube 34.

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The apertures comprise openings which can be of any appropriate shape. For example, we have produced blankets with elongated apertures, approximately 1/4 inch in length.

Our invention is illustrated as we intend for it to be used in a second aspect including a foot drape in Figure 7. The foot end 14 of the thermal blanket 10 is modified to provide an uninflated drape forming section 70 formed by a rearward extension of the base sheet 50/52 and a noninflatable portion of the heat-sealable plastic bonded to the base sheet. The drape forming sheet 70 has sides 72 extending parallel to and rearwardly from the outside edge of the edge seams 43, and a rear edge 74. Optionally, the drape-forming sheet 70 further includes a pair of V-shaped cuts 76 in the rear corners thereof. The V-shaped cuts 76

are formed by converging cuts 78 and 80, extending inwardly sides 72 the one of the and rear respectively, to a point of intersection 82. As-shown in Figure 7, the drape-forming section 70 may be formed into a foot drape 90 that includes a pair of side portions 92, a The drape 90 is rear portion 94 and an upper portion 96. so formed by joining the edges 78 and 80 of the V-shaped cuts 76 to form a pair of seams 98. To form the seams 98, the V-shaped cut edges 78 and 80 may be folded about respective lines 100 and 102 that parallel the edges 78 and 280, as shown in Figure 6. The resulting respective folded surfaces 104 and 106 may then be fastened together by Wappropriate means such as heat sealing. Joining the surfaces 104 and 106 forms a crease 108 and transforms the Itwo dimensional drape forming section 70 into the three dimensional drape 90.

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The resultant drape 90 is non-inflatable but erectable under the force of the heated medium circulating around the patient. The drape 90 thus traps and retains heat around the patient's feet to warm the feet. As shown in Figure 7, the drape 90 also insulates the bare skin of the feet from excessive conductive heat from the inflating hose 70 in the event the hose is oriented in a position wherein it might otherwise come in contact with the feet. Patient warming and comfort is thus further enhanced.

Our invention is illustrated as we intend for it to be used in a third aspect as an inflatable lower body covering in Figures 8 and 9. This covering warms convectively by exhausting warm air onto a patient. The thermal covering in this case is similar in all respects to the covering shown in Figs. 6 and 7, except that the covering may be shortened

to cover only the pelvic area and lower extremities of the Moreover, the head end of the covering may be modified to provide an open flat working area for the placement of instrumentation and to improve visualization of the care site, as shown in Fig. 9. As in the case of the thermal coverings discussed above, the covering 110 of Figures 8 and 9 includes a head end 112, a foot end 114, a pair of lateral edges 115, and an inflation inlet cuff 116 to which may be connected through a heater tube 20 to a heater/blower assembly such as the assembly 18 shown in Figure 1. As shown in Figure 9, the covering 110 may be inflated to form a Quonset hut-like structure with iguilted upper surface 121. Like the thermal covering 10, a pattern of apertures on the undersurface of the blanket 110 mconvectively delivers the inflating heated air into the interior space enclosed by the erected thermal blanket.

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Alternatively, the head end of the quilted upper surface 121 could extend directly from one edge 115 to the tother edge 115 without the provision of a non-inflated blanket recess 122, as shown in Fig. 8. Further, adhesive strip 124 made of an adhesive material may be attached to the head end 112 of the covering 110 and extend between the edges 110. As shown in Fig. 8a, the adhesive strip 124 is mounted with its adhesive side oriented toward the base sheet, which includes an underside layer 150 formed from a flexible material capable of bonding to a layer 152 of heat sealable plastic. The layers 150/152 are formed in the same manner as the layers 50/52 shown in Fig. 3 and described above. Mounted to the underside of the adhesive strip 124 is a backing strip 125, which may be

positioned partially between the adhesive strip 124 and the layer 152 to prevent inadvertent peel-off.

As shown in Figure 9, the adhesive strip 124 may be adhered above the patient's pelvic and groin area to prevent the migration of air from inside the covering 110 to the care site. Moreover, the optional non-inflated recess 122 may be large and well-defined in order to improve visualization of the operating field and provide sufficient working area for resting instruments or other items during the rendering of care to a patient 126.

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Like its counterpart covering 10, the covering 110 includes a parallel array of elongated tubes of which 130 $oxedsymbol{\sqcup}$ and 132 are the lateralmost tubes, 134 is the center tube, and the tubes 138 are arrayed between one Tlateralmost tubes and the center tube. The thermal covering 110 further includes a non-inflated yet erectable foot drape for retaining a thermal medium patient's feet. As in the covering shown in Figure 6, the mcovering 110 is provided with a non-inflated drape forming section 170 extending rearwardly from the foot end 114. The covering 170 includes a pair of sides 172 and a rear edge 174. Moreover, the drape forming sheet 170 includes a pair of V-shaped cuts 176 in the rear corner thereof. shown in Figure 9, the drape forming section 170 may be formed into an erectable foot drape 190 that includes a pair of side portions 192, a rear portion 194, and an upper portion 196. As in the covering 10, the drape 190 of the covering 110 is formed by joining the edges of the V-shaped cuts 176 to form a pair of seams 198.

As with the longer full-body thermal blanket of Figs. 1 and 2, the covering 110 may be provided without a foot

drape as appropriate. In that case, it may be desirable to slideably mount a protective sleeve 200 over the heater tube 20 to prevent the tube from contacting the patient.

Advantageously, it will be observed that the lower body warming cover 110 maintains a thermal medium around the pelvic and groin area and lower extremities of the patient, while at the same time exposing the patient's torso and head as may be necessary for the provision of medical care and treatment to those areas.

Alternatively, or in combination with the lower body thermal covering 110, an upper body thermal covering 210 could be provided as shown in Figures 10 and 11. body thermal covering 210 is structurally and functionally isimilar in most respects to the thermal coverings 10 and ¶110 discussed above. Thus, the thermal covering includes a head end 212, a foot end 214, a pair of lateral Cedges 215, and an inflation inlet cuff 216 which may be connected through a heater tube 20 to an external Theater/blower assembly such as the assembly 18 shown in The thermal covering 210 further includes a Figure 1. quilted upper surface 22, which may have non-inflated recess 222 located at the foot end of the covering, as shown in Fig. 11. Thus, with the upper torso and arms of the patient being thermally bathed, the uninflated recess 222 permits observation of the patient's middle torso from almost any location with respect to the thermal covering 210.

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Alternatively, as shown in Fig. 10, the quilted upper surface 221 could extend across the entire expanse of the covering between the edges 215 such that no uninflated recess 222 is formed. It is preferable in most cases,

however, to provide a recess 223 in the quilted upper surface 221 and the foot end 214 of the covering 210 to accommodate the curvature of the patient's torso, as shown in Fig. 11.

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There may be additionally provided an adhesive strip 224 mounted to the foot end 214 of the covering 210. shown in Fig. 10a, the adhesive strip 224 is mounted with the adhesive side facing the base sheet, which includes an underside layer 250 formed from a flexible material capable of bonding to a layer 252 of heat sealable plastic. Clayers 250/252 are formed in the same manner as the layers 50/52 shown in Fig. 3 and described above. Mounted to the wunderside of the adhesive strip 224 is a backing strip 225, which may be positioned partially between the adhesive Instrip 224 and the layer 252 to prevent inadvertent \square peel-off. As shown in Fig. 11, the adhesive strip 224 may mbe adhered to the patient's torso to prevent the migration of air toward the care site.

covering 210 further includes an array elongated tubes of which 230 and 232 are the lateral most 42 tubes, 234 is the center tube and the tubes 238 are arrayed between one of the lateral most tubes and center tube. addition, the thermal covering 210 includes a cutout area 240 centrally positioned at the head end 212 The cutout 240 is formed by truncating the covering. lateralmost tube 230 and an adjacent tube 238. The recess 240 permits observation of the patient's head and neck from almost any location with respect to the thermal blanket It also assists in thermally covering the patient's shoulders and arms without covering the patient's face. shown in Figures 10 and 11, the bottom layer 250/252 of the

covering 210 may extend slightly beyond lateral edges 215 or the head end 212, or it may be coextensive therewith.

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As shown in Figure 11, the thermal covering 210 is positioned over the patient's upper torso and arms so as to thermally control those areas while leaving the patient's exposed for the provision of care. lower torso indicated, the thermal covering 210 may be used alone or in combination with the thermal covering 110 depending on the location of the care site. Thus, various selected portions patient may selectively warmed with be Pillustrated thermal coverings while care and treatment may be rendered to other areas. In addition, a plastic head drape 260 may be adhesively mounted to the covering 210 over the patient's chest, and adjacent the head end 230. The plastic head drape 260 is placed over the patient's head and one or more vents 270 may be provided to direct warmed air to the head area.

In a preferred method of operation, one or both of the coverings 110 and 210 may be selectively employed on a patient to warm selected portions of the patient while permitting other portions to remain exposed for treatment. In utilizing the coverings 110 and 210, either alone or in combination, the covering 110 or 210 is first placed over the patient. The adhesive backing 125 or 225 is removed from the adhesive strip 124 or 224 and the adhesive strip is adhered to the patient to prevent the migration of air toward the care site. The hose 20 is then attached to the covering, an appropriate temperature is selected on the heater unit 18 and the unit 18 is activated. For the covering 110, the protective heater tube 200 cover may also be used when the cover does not include a foot drape. For

the covering 210, the head drape 260 may be adhered to the quilted portion 221 over the patient's chest and draped over the patient's head. As a final measure, a conventional blanket may be placed over the covering 110 or 210. During operation, the patient's temperature should be monitored regularly and the air temperature setting of the heater unit 18 adjusted accordingly.

Many modifications and variations of our invention will be evident to those skilled in the art. For example, thermal coverings for additional selected patient areas could be implemented depending on the location of the care site and the need for thermally maintaining other areas. It is understood that such variations may deviate from specific teachings of this description without departing from the essence of the invention, which is expressed in the following claims.

We claim:

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CLAIMS

- 1. In a self-erecting, inflatable thermal blanket for covering and bathing a person in a thermally-controlled inflating medium, the improvement comprising:
 - a flexible base sheet having a head end, a foot end, two edges, and a plurality of apertures;

an overlaying flexible material sheet attached to a first surface of said base sheet by a plurality of discontinuous seams which form said overlaying material sheet into a plurality of communicating, inflatable chambers, said apertures opening through said base sheet into said chambers;

a continuous seam between said overlaying material sheet and said base sheet near said head end which closes ends of said inflatable chambers;

a non-inflatable section of said thermal blanket extending substantially between said continuous seam and said head end and including an end portion of said flexible sheet; and

said thermal blanket being sized to extend from a patient's pelvic and groin area to the patient's feet.

- 2. The improvement of claim 1 further including a non-inflatable foot drape.
- 3. The improvement of claim 1 further including an adhesive strip at said head end to adhere said head end to a patient and prevent migration of air towards a care site.

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- 4. In a self-erecting, inflatable thermal blanket for covering and bathing a person in a thermally-controlled inflating medium, the improvement comprising:
 - a flexible base sheet having a head end, a foot end, two edges, and a plurality of apertures;

an overlaying flexible material sheet attached to a first surface of said base sheet by a plurality of discontinuous seams which form said overlaying material sheet into a plurality of communicating, inflatable chambers, said apertures opening through said base sheet into said chambers;

- a continuous seam between said overlaying material sheet and said base sheet near said head end which closes ends of said inflatable chambers;
- a non-inflatable section of said thermal blanket extending substantially between said continuous seam and said head end and including an end portion of said flexible sheet; and

said thermal blanket being sized to extend from a patient's neck to the patient's upper torso and to cover the patient's arms and shoulders.

- 5. The improvement of claim 4 further including a flat uninflatable section at said foot end.
- 6. The improvement of claim 4 further including an adhesive strip at said foot end to adhere said foot end to a patient and prevent migration of air towards a care site.

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- 7. The improvement of claim 4 further including a head drape at said head end to drape over a patient's head and a vent for directing heated air under said head drape.
- 8. An inflatable thermal blanket for convectively controlling the temperature of a human body, comprising:

a self-erecting inflatable covering with a head end, a foot end, two edges, and an undersurface;

an inflating inlet for admitting a thermally-controlled inflating medium into said covering;

an array of apertures in said undersurface for exhausting a thermally controlled inflating medium from said covering to said undersurface;

means in said inflatable covering for equalizing the temperature of a thermally controlled inflating medium in said inflatable covering by circulating said inflating medium toward said two edges;

an uninflatable extension in said inflatable covering at said head end; and

said thermal blanket being sized to extend from a patient's pelvic and groin area to the patient's feet.

- 9. The thermal blanket of claim 8 further including a non-inflatable foot drape.
- 10. The thermal blanket of claim 8 further including an adhesive strip at said head end to adhere said head end to a patient and prevent migration of air towards a care site.

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11. An inflatable thermal blanket for convectively controlling the temperature of a human body, comprising:

a self-erecting inflatable covering with a head end, a foot end, two edges, and an undersurface;

an inflating inlet for admitting a thermally-controlled inflating medium into said covering;

an array of apertures in said undersurface for exhausting a thermally controlled inflating medium from said covering to said undersurface;

means in said inflatable covering for equalizing the temperature of a thermally controlled inflating medium in said inflatable covering by circulating said inflating medium toward said two edges;

an uninflatable extension in said inflatable covering at said head end; and

said blanket being sized to extend from a patient's neck to the patient's upper torso and to cover the patient's arms and shoulders.

- 12. The thermal blanket of claim 11 further including a flat uninflatable section of said foot end.
- 13. The improvement of claim 11 further including an adhesive strip at said foot end to adhere said foot end to a patient and prevent migration of air towards a care site.
- 14. The improvement of claim 11 further including a head drape at said head end to drape over a patient's head and a vent for directing heated air under said head drape.

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15. In a self-erecting, inflatable thermal blanket for covering and bathing a person in a thermally-controlled inflating medium, the improvement comprising:

a flexible base sheet having a head end, a foot end, two edges, and a plurality of apertures;

an overlaying flexible material sheet attached to a first surface of said base sheet by a plurality of discontinuous seams which form said overlaying material sheet into a plurality of communicating, inflatable chambers, said apertures opening through said base sheet into said chambers;

a continuous seam between said overlaying material sheet and said base sheet near said head end which closes ends of said inflatable chambers;

a non-inflatable section of said thermal blanket extending substantially between said continuous seam and said head end and including an end portion of said flexible sheet; and

a flexible heater hose attached to said thermal blanket to provide heated air to said inflatable chambers, said flexible heater hose including a protective sleeve slideably disposed thereon to prevent hose contact with a patient.

16. An inflatable thermal blanket for convectively controlling the temperature of a human body, comprising:

a self-erecting inflatable covering with a head end, a foot end, two edges, and an undersurface;

an inflating inlet for admitting a thermally-controlled inflating medium into said covering;

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an array of apertures in said undersurface for exhausting a thermally controlled inflating medium from said covering to said undersurface;

means in said inflatable covering for equalizing the temperature of a thermally controlled inflating medium in said inflatable covering by circulating said inflating medium toward said two edges;

an uninflatable extension in said inflatable covering at said head end; and

a flexible heater hose attached to said thermal blanket to provide heated air to said inflatable chambers, said flexible heater hose including a protective sleeve slideably disposed thereon to prevent hose contact with a patient.

17. A method for thermally warming a selected portion or portions of a patient for rendering care to other portions of the patient, comprising the steps of:

selecting one or more inflatable thermal blankets sized to cover a portion or portions of a patient to be thermally warmed so that care may be administered to other portions of the patient, said inflatable thermal blanket(s) being of a type that comprise(s):

a self-erecting inflatable covering with a head end, a foot end, two edges, and an undersurface; and

an inflating inlet for admitting a thermally-controlled inflating medium into said covering;

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an array of apertures in said undersurface for exhausting a thermally controlled inflating medium from said covering to said undersurface;

means in said inflatable covering for equalizing the temperature of a thermally controlled inflating medium in said inflatable covering by circulating said inflating medium toward said two edges;

an uninflatable extension in said inflatable covering at said head end or said foot end; and

an adhesive strip at said head end or said foot end having an adhesive portion facing in the direction of said thermal blanket undersurface and a removable backing covering said adhesive portion;

said method further comprising the steps of:

placing the thermal blanket(s) over the portion(s) of the patient to be thermally warmed such that the adhesive portion of said blanket(s) is oriented toward a care site;

removing the backing from said adhesive portion and adhering the adhesive to the patient to prevent the migration of air towards a care site;

attaching a heating tube or tubes from a heating unit to said thermal blanket(s);

selecting an appropriate temperature and activating the heating unit; and

monitoring the patient's temperature regularly and adjusting the heating unit temperature as required by the patient's temperature.

18. The method of claim 17 wherein the area(s) of a patient to be covered include(s) the area extending from the patient's pelvic and groin area to the patient's feet.

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- 19. The method of claim 18 wherein said thermal blanket extends from the patient's pelvic and groin area to the patient's feet and wherein the adhesive portion of said thermal blanket is adhered to the patient above the patient's pelvic and groin area.
- 20. The method of claim 19 further including the step
 of placing a protective sleeve over the heater tube
 adjacent said thermal blanket to prevent the heater tube
 from contacting the patient.
 - 21. The method of claim 17 wherein the area(s) of a patient to be covered include(s) the area extending from the patient's neck area to the patient's chest and including the patient's arms.
 - 22. The method of claim 21 wherein said thermal blanket extends from the patient's neck area to the patient's chest and also covers the patient's arms and wherein the adhesive portion of said thermal blanket is adhered to the patient's chest.
 - 23. The method of claim 22 further including the step of adhering a head drape on or near said head end of said thermal blanket and draping the head drape loosely over the patient's head.

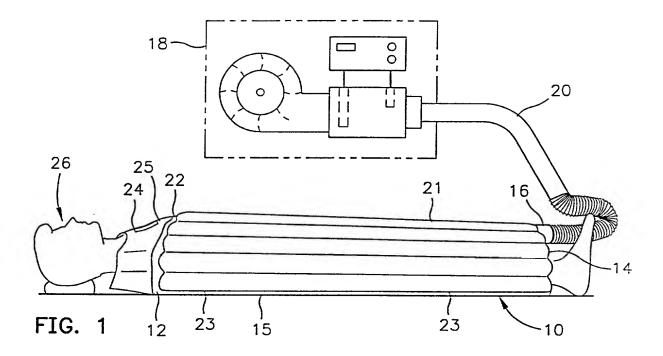
- 24. The method of claim 17 further including the step of draping a conventional blanket or blankets over said thermal blanket(s).
- 25. A thermal care system for thermally warming a patient comprising:
 - an inflatable thermal blanket having at least one inflatable chamber therein and an air inlet for admitting air to said chamber;
 - a heater/blower assembly providing a source of heated air;
 - a heater tube extending from said heater/blower assembly to said thermal blanket air inlet; and
 - a protective sleeve slideably disposed over said heater tube adjacent said thermal blanket air inlet to prevent said heater tube from contacting the patient.

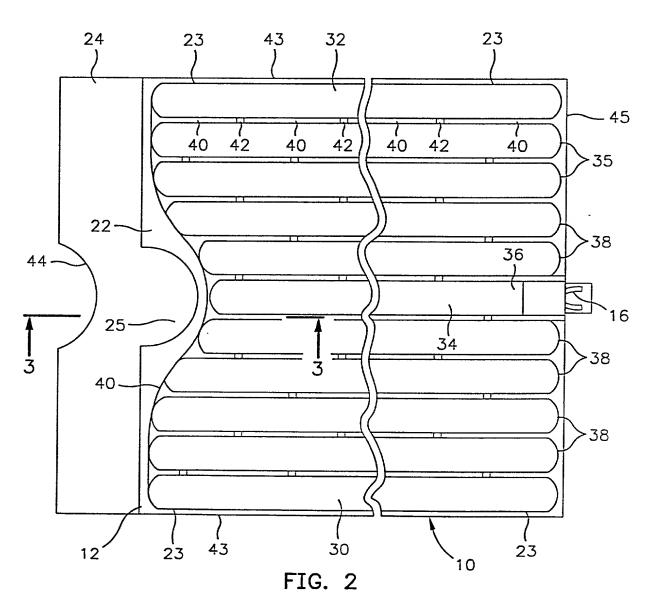
THERMAL BLANKET

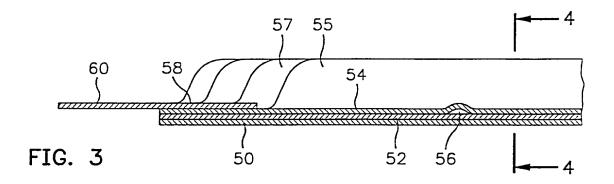
ABSTRACT

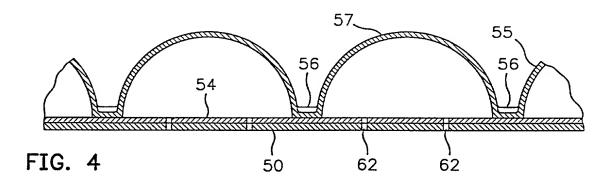
A thermal blanket includes an inflatable covering with a head end, a foot end, two edges and an undersurface. covering is inflated through an inlet at the foot end by a thermally-controlled inflating medium. An aperture array on the undersurface of the covering exhausts the thermally controlled inflating medium from the covering. port openings are provided that the edges of the covering to vent the inflating medium, which enhances circulation of the thermally-controlled medium through the cover. uninflatable section is provided at the head end, together with an absorbent bib attached to the covering, adjacent the uninflatable section. An uninflatable section may also be provided at the foot end having a pair of seams to form Tan erectable drape section. When inflated, the thermal blanket self-erects and provides bath a ithermally-controlled inflating medium to the interior of the erected structure. The enhanced circulation of the medium through the covers maintains a relatively high average temperature under the blanket and a relatively uniform distribution of temperature in the inflating medium exhausted through the apertures structure's interior. When the structure covers a patient, the uninflatable section at the head end provides a relatively unobstructed view of the patient's face, while the absorbent bib maintains a relatively sanitary environment in the area beneath the patient's head. uninflatable section at the foot end retains heat from the

inflating medium to warm the patient's feet and insulate the bare skin of the feet from excessive conductive heat from the hose connected to the inflation inlet. The thermal blanket may be sized to cover selected areas of a patient such as the upper body, including the chest, arms, or shoulders, or the lower body, including the pelvic and groin area and the legs.









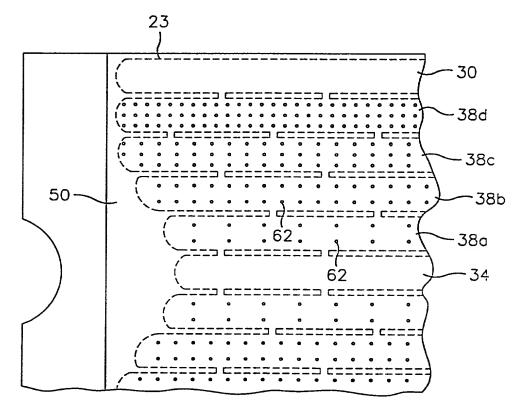
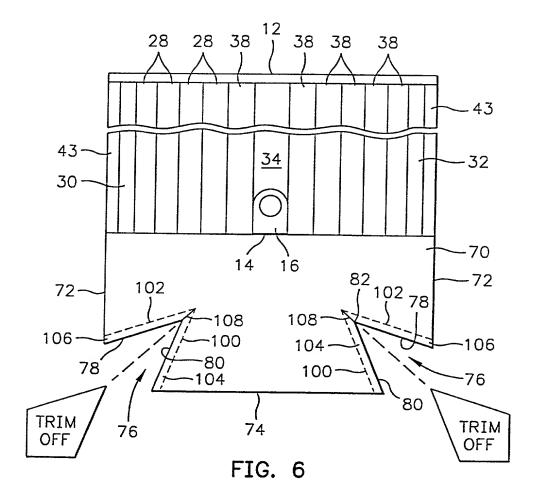
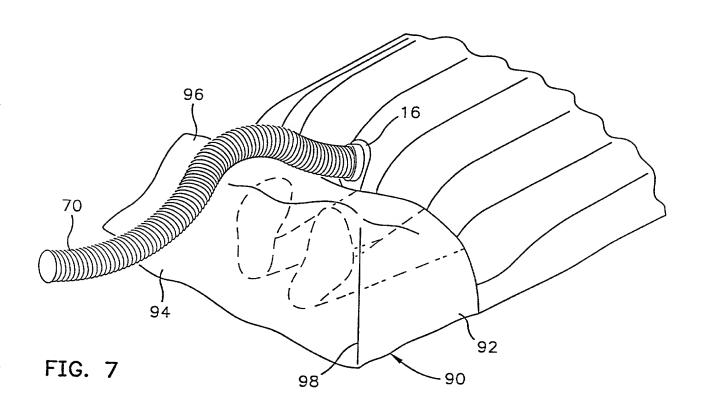


FIG. 5





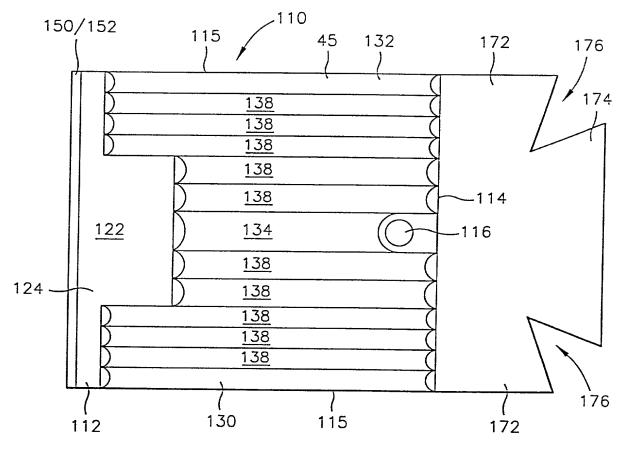
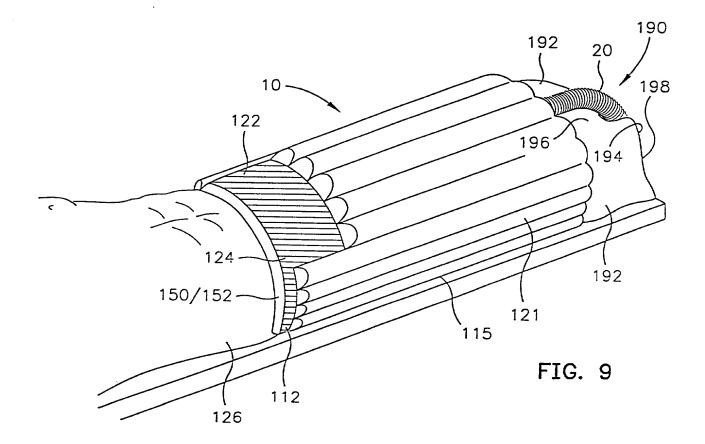


FIG. 8



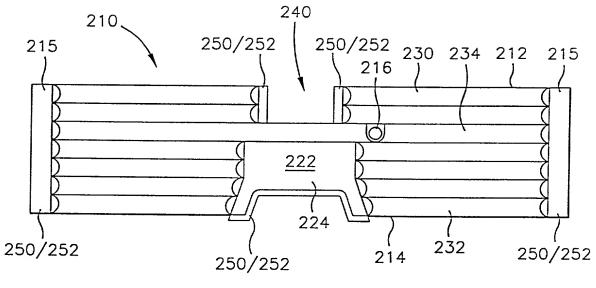
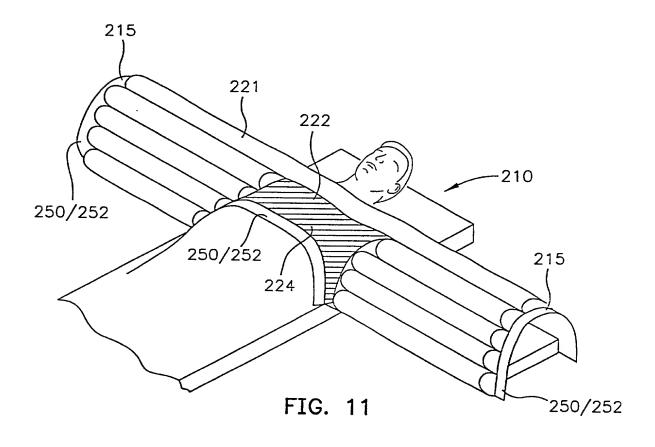


FIG. 10



Attorney's Doc' & No. 0603
As a below named inventor, I hereby declare that:
my residence, post office address and citizenship are as stated below next to my name; I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: THERMAL BLANKET
the specification of which
X is attached hereto
was filed on, as Application Serial No, and was amended on (if applicable)
I hereby state that I have reviewed and understand the contents of the above-identified Specification, including the Claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37 CFR 1.56(a).
I hereby claim foreign priority benefits under Title 35 USC 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which
priority is claimed: Priority Claimed
(Number) (Country) (Day/Month/Year Filed) (Yes) (No)
(Number) (Country) (Day/Month/Year Filed) (Yes) (No)
I hereby claim the benefit under Title 35 USC 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35 USC 112, I acknowledge the duty to disclose material information as defined in Title 37 CFR 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.
(App. Serial No.) (Filing Date) (Status, i.e. patented, pending, abandoned)
(App. Serial No.) (Filing Date) (Status, i.e. patented, pending, abandoned)
I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the U.S. Patent and Trademark Office connected therewith Freling E. Baker, Reg. #24,078; Lawrence A. Maxham, Reg. # 24,483; Michael H. Jester, Reg. #28,022; Terrance A. Meador, Reg. #30,298; and Walter W. Duft, Reg. #31,948. Address all telephone calls to Walter W. Duft at Telephone No. (619) 233-9004 and address all correspondence to Walter W. Duft; BAKER, MAXHAM, JESTER & MEADOR, 110 West "C" Street, Suite 1202, San Diego, California, 92101.
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.
FULL NAME OF SOLE OR FIRST INVENTOR INVENTOR'S SIGNATURE DATE
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Page 2/Declaration/Power of Attorney

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RESIDENCE	And the second s	CITIZENSHIP
POST OFFICE ADDRESS		
FULL NAME OF FIFTH JOINT INVENTOR IF ANY	INVENTOR'S SIGNATURE	DATE
RESIDENCE		CITIZENSHIP
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